



SonoCiné Automated Whole Breast Cancer Screening System Receives Approval from Health Canada

RENO, Nevada (January 16, 2012) – [SonoCiné](#), Inc., the leading innovator of [automated whole breast ultrasound \(AWBU\)](#) screening systems for early detection of breast cancer announced today that it has been granted a Class 2 Medical Device License by the Medical Devices Bureau of Health Canada to sell and market its Automated Whole Breast Acquisition Screening System (AWBASS) as an adjunct to mammography for screening asymptomatic women for breast cancer.

The SonoCiné AWBASS is an accessory to already approved ultrasound scanners, providing computer controlled automatic acquisition and subsequent dynamic review of closely spaced consecutive 2D images of the entire breast and lower axilla. The integration of SonoCiné AWBASS and a standard ultrasound scanner forms an Automated Whole Breast Ultrasound (AWBU) screening system.

The SonoCiné system received FDA 510(k) clearance in the U.S. in 2008 as an [adjunct to mammography](#), but not a replacement for screening mammography, and in 2010 the results of the [first breast cancer screening trial](#) were published in the peer reviewed medical journal, *European Radiology*.

This blinded, prospective, multi-center study, (*Kelly K, Dean J, et al, Breast cancer detection using automated whole breast ultrasound and mammography in radiographically dense breasts, Eur Radiol (2010) 20: 734–742*) was designed to compare the screening performance of mammography alone with that of mammography plus SonoCiné. In the study, 6,425 examinations were performed, resulting in the combined [detection of twice as many cancers as mammography alone](#), and three times as many small 5-10mm (2/10" – 4/10") cancers as were detected with mammography alone.

"We are very pleased that we can now move forward and make the SonoCiné breast cancer screening examination available to the women of Canada", commented Karsten Damgaard-Iversen, CEO of SonoCiné, Inc., and added, "To date more than 18,000 [breast screening examinations](#) have been performed using the SonoCiné system, and our users continue to report on the [high cancer detection](#) and low recall rates that our proprietary image acquisition and dynamic review process enables them to consistently achieve".

About the SonoCiné AWBU system and SonoCiné, Inc:

The [SonoCiné system](#) was invented and engineered specifically for integration with standard ultrasound scanners to provide radiologists with an effective, systematic and automated screening examination for the early detection of mammographically occult breast cancers in asymptomatic women.

The high cancer detection performance reported by clinical users of SonoCiné AWBU is the result of a number of important system characteristics. These include separating the image data acquisition from the radiologist's review, automating and computer-controlling the screening of the entire breast and lower axillary lymph nodes, and maximizing lesion visualization and detectability using the company's [proprietary dynamic review software](#). The risk-free procedure is fully documented, quality-controlled and pain-free.

Unlike mammography, the SonoCiné AWBU procedure requires no breast compression or x-ray radiation, and unlike MRI and MBI/BSGI, it requires neither a contrast agent, nor a radioactive tracer.

Based in Reno, NV, SonoCiné, Inc., is a privately owned research, development and manufacturing company with focus on early [breast cancer detection](#).

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